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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/547,206	05/19/2006	Alain Jacquet	VB60107	4723

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EXAMINER	
ROONEY, NORA MAUREEN	

ART UNIT	PAPER NUMBER
1644	

NOTIFICATION DATE	DELIVERY MODE
04/09/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

US_cipkop@gsk.com

Office Action Summary	Application No.	Applicant(s)	
	10/547,206	JACQUET, ALAIN	
	Examiner	Art Unit	
	PHUONG HUYNH	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *One* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 August 2005*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-30* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-30 are pending.

The following is noted.

- The SEQ ID NO: 15, 17, 19, 20 and 21 in sequence listing submitted August 26, 2005 are inconsistent with the SEQ ID NO: 15, 17, 19, 21 and 22 disclosed in the specification at page 78-82, 83 and 94 and the claims as filed. Specifically, SEQ ID NO: 15, 17, and 19 are protein sequences while SEQ ID NO: 20 and 21 are nucleic acid sequences in the specification. However, the sequence of SEQ ID NO: 15, SEQ ID NO: 17 and SEQ ID NO: 19 in the sequence listing are nucleic acid sequences. Applicants are required to correct the paper copy and the computer copy of the sequence listings in response to this Office Action.

Election/Restriction

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Invention 1 Claims 1, 3 and 8-12, drawn to a recombinant *Dermatophagoides pteronyssinus* Der p 1 protein allergen derivative wherein said allergen derivative has a significantly reduced allergenic activity compared to that the wild-type allergen in which said derivative has been genetically mutated and in which the mutant comprises the three following mutations: a mutation of the cysteine 71 residue, a mutation of the cysteine 103 residue and a mutation of the cysteine 117 residue; and immunogenic composition comprising said recombinant protein, and a recombinant mutant allergen having the sequence of SEQ ID NO: 15.

Invention 2 Claims 2 and 3, drawn to a recombinant *Dermatophagoides pteronyssinus* Der p 1 protein allergen derivative wherein said allergen derivative has a significantly reduced allergenic activity compared to that the wild-type allergen in which said derivative has been genetically mutated and in which the mutant comprises a deletion of amino acid residues 147 to 160 of Der p 1 or residues 227-140 of ProDer p 1 and a recombinant mutant allergen having the sequence of SEQ ID NO: 17.

Invention 3 Claims 4-7, 20, and 22-23, drawn to an isolated nucleic acid molecule encoding *Dermatophagoides pteronyssinus* Der p 1 protein allergen derivative in which said derivative has been genetically mutated and in which the mutant comprises the three following mutations: a mutation of the cysteine 71 residue, a mutation of the cysteine 103 residue and a mutation of the cysteine 117 residue; a recombinant mutant allergen having the sequence of SEQ ID NO: 15, an expression vector containing said nucleic acid molecule; host cell transformed with said nucleic acid molecule.

Invention 4 Claim 13, drawn to use of a *Dermatophagoides pteronyssinus* Der p 1 protein allergen derivative in the manufacture of a medicament, in which said derivative has been genetically mutated and in which the mutant comprises the three following mutations: a mutation of the cysteine 71 residue, a mutation of the cysteine 103 residue and a mutation of the cysteine 117 residue.

Invention 5 Claim 14, drawn to a method of treating a patient suffering form or preventing a patient susceptible to allergic responses comprising administering *Dermatophagoides pteronyssinus* Der p 1 protein allergen derivative, in which said derivative has been genetically mutated and in which the mutant comprises the three following mutations: a mutation of the cysteine 71 residue, a mutation of the cysteine 103 residue and a mutation of the cysteine 117 residue.

Invention 6 Claims 15-19 and 24-28, drawn to *Dermatophagoides pteronyssinus* ProDer p 3 or PreProDer p 3 protein allergen or derivative thereof, wherein said ProDer p 3, PreProDer p 3 or allergen derivative has a significantly reduced allergenic activity compared to Der p3; and immunogenic composition comprising said protein, and a recombinant allergen having the sequence of SEQ ID NO: 19.

Invention 7 Claim 21, drawn to an isolated nucleic acid molecule encoding PreProDer p3 having the sequence of SEQ ID NO: 20 and SEQ ID NO: 21.

Invention 8. Claim 29, drawn to use of a *Dermatophagoides pteronyssinus* ProDer p 3 or PreProDer p 3 protein allergen or derivative thereof in the manufacture of a medicament.

Invention 9. Claim 30, drawn to a method of treating a patient suffering form or preventing a patient susceptible to allergic responses comprising administering a *Dermatophagoides pteronyssinus* ProDer p 3 or PreProDer p 3 protein allergen or derivative thereof.

The inventions listed as Inventions 1-9 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

There is no same or corresponding technical feature shared between Inventions 1-5 and Inventions 6-9. Inventions 1-5 encompass hypoallergenic Der p 1 proteins, while Inventions 6-9 encompass hypoallergenic Der p 3 proteins. The Der p 1 proteins and Der p 3 proteins of the instant application have no structural features and properties that are shared between each other.

There is no same or corresponding technical feature shared between Invention 1 and Invention 2. The Der p 1 protein of Invention 1 comprising a mutation of the cysteine 71 residue, a mutation of the cysteine 103 residue and a mutation of the cysteine 117 residue; and the Der p 1 protein of Invention 2 comprising a deletion of amino acid residues 147 to 160 of Der p 1 or residues 227-140 of ProDer p 1 have no structural features and properties that are shared between each other.

A same or corresponding technical feature shared between Invention 1 and Inventions 3-5 is a Der p 1 protein comprising a mutation of the cysteine 71 residue, a mutation of the cysteine 103 residue and a mutation of the cysteine 117 residue .

However, the combination WO 01/96385 (form PTO-1449 filed 08/26/05) in view of WO 02/074250 (form PTO-1449 filed 08/26/05) and WO 99/25823 (form PTO-1449 filed 08/26/05) teach such Der p 1 protein.

WO 01/96385 teaches hypoallergenic Der p1 mutant proteins wherein cysteines at positions 4, 31, and 65 have been mutated. See entire document, especially page 26, lines 20-24.

WO 01/96385 does not teach hypoallergenic Der p1 proteins having mutations of cysteines at positions 71, 103, and 117.

WO 02/074250 teaches that a broad class of allergens can be obtained by mutating cysteines involved in disulfide bonds. See entire document, especially page 3, lines 16-30.

WO 99/25823 teaches that hypoallergenic mutants of Der p 1 can be obtained by mutating the cysteines involved in disulfide bonds as an alternative to abolishing Der p 1 catalytic activity, where the allergenicity of Der p 1 is linked to its catalytic activity. See entire document, especially page 6, line 30 to page 9; and claim 10.

Therefore, it would have been obvious to one of ordinary skill in the art to mutate the Der p1 protein such that it has mutations of cysteines at positions 71, 103, and 117. One of ordinary skill in the art would have been motivated to do this because WO 99/25823 teaches that hypoallergenic mutants of Der p 1 can be obtained by mutating the cysteines involved in disulfide bonds as an alternative to abolishing Der p 1 catalytic activity, where the allergenicity of Der p 1 is linked to its catalytic activity. Furthermore, WO 02/074250 teaches that a broad class of allergens can be obtained by mutating cysteines involved in disulfide bonds.

Thus, the same or corresponding technical feature is not special since it was known in the prior art and therefore cannot make a contribution over the prior art. Since the inventions lack the same or corresponding special technical feature, then the inventions listed as Inventions 1 and 3-5 are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims

to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong Huynh "NEON" whose telephone number is (571) 272-0846. The examiner can normally be reached Monday through Friday from 9:00 am to 5:30 p.m. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The IFW official Fax number is (571) 273-8300.

Any information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Phuong Huynh/
Primary Examiner, Art Unit 1644
March 28, 2008

Application Number	Application/Control No.	Applicant(s)/Patent under Reexamination	
	10/547,206	JACQUET, ALAIN	
	Examiner	Art Unit	
	PHUONG HUYNH	1644	